IN THE UNITED STATES DISRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA

BRENDA GRAHAM AS PERSONAL REPRESENTATIVE OF ESTATE OF THOMAS BELLAMY (DECEASED), PLAINTIFF, v. KONINKLIJKE PHILIPS N.V.; PHILIPS NORTH AMERICA LLC; PHILIPS HOLDING USA, INC.; PHILIPS RS NORTH AMERICA LLC f/k/a RESPIRONICS, INC.; PHILIPS RS NORTH AMERICA HOLDING CORPORATION; POLYTECH; AND POLYMER MOLDED PRODUCTS, DEFENDANTS.	Civil Action No. 2:24-cv-03408-BHH **COMPLAINT** **Jury Trial Demanded**

COMPLAINT

Plaintiff Brenda Graham as Personal Representative of the Estate of Thomas Bellamy, by and through his undersigned counsel, hereby submits the following Complaint and Demand for Jury Trial against Defendants Koninklijke Philips N.V. ("Royal Philips"); Philips North America LLC ("Philips NA"); Philips Holding USA, Inc. ("PHUSA"); Philips RS North America LLC f/k/a Respironics, Inc. ("Philips RS"); Philips RS North America Holding Corporation ("RS Holding") (collectively referred to as "Philips"); PolyTech; and Polymer Molded Products ("PMP") (collectively referred to herein as "PolyTech") and alleges the following upon personal knowledge and belief as well as investigation of counsel:

INTRODUCTION

1. Philips designs, manufactures, markets, imports, sells and distributes a variety of sleep and respiratory care products.

2. Philips designs, manufactures, markets, imports, sells and distributes a variety of Continuous Positive Airway Pressure ("CPAP") and BiLevel Positive Airway Pressure ("BiPAP") devices for patients with various types of sleep apnea.

3. Philips also designs, manufactures, markets, imports, sells and distributes a variety of mechanical ventilator devices for patients with respiratory failure conditions.

4. On June 14, 2021, Philips issued a voluntary recall notification for many of its CPAP and BiLevel PAP devices as well as a number of its mechanical ventilator devices (the "Recalled Devices").

5. In its voluntary recall notification, Philips advised of potential health risks related to the polyester-based polyurethane ("PE-PUR") sound abatement foam used in the affected devices.

6. Philips informed patients using these affected devices of potential risks from exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material, specifically the PE-PUR.

7. Specifically, Philips notified patients that the risks related to the issues with the sound abatement foam include headache, irritation, inflammation, respiratory issues and possible toxic and carcinogenic effects.

8. Philips announced these hazards could result in "serious injury which can be life-threatening or cause permanent impairment."

9. Philips knew about these very substantial and material risks long before they announced the voluntary recall. Patients who use the Recalled Devices have complained about black particles

in their machines for years. Philips publicly warned only its shareholders and its customers about these hazards on or about April 26, 2021 and did not warn the individual users until they voluntarily recalled the Recalled Devices on June 14, 2021.

10. On July 22, 2021, The U.S. Food & Drug Administration ("FDA") identified Philips' recall as a Class 1 Recall, the most serious type of recall which includes cautioning that use of these devices may cause serious injury or death.

11. Plaintiff's Decedent, Thomas Bellamy, was diagnosed with obstructive sleep apnea syndrome prior to 2018.

12. Plaintiff's Decedent was prescribed and purchased Philips' now-recalled device, DreamStation Auto CPAP DOM, serial number J162877120D07, to treat his obstructive sleep apnea syndrome prior to 2018. Plaintiff used this device as prescribed by his physician. More specifically, Plaintiff used this device on a daily basis for approximately four years, until he could obtain a new and safe alternative.

13. The DreamStation recalled device will be referred to as the "Subject Device."

14. After using the Subject Device, Decedent was diagnosed with a cancer.

15. As a direct and proximate result of Philips' conduct, Decedent has suffered serious and substantial life-altering injuries, pain and suffering and ultimately death.

16. As a direct and proximate result of the Subject Device designed, manufactured, marketed, imported, sold and distributed by Philips, Decedent has suffered physical, emotional and financial injuries, including his diagnosis of cancer and death.

17. Plaintiff's Decedent would not have purchased and used these products if he had known they were defective, contained toxic and carcinogenic by-products and would be subject to a recall

for containing defective materials. As a result of the recall, Decedent was forced to seek an alternative option for his condition.

PLAINTIFF

18. Plaintiff is the surviving sister and lawfully appointed Personal Representative of Decedent. Decedent was an adult resident and citizen of Conway, Horry County, South Carolina.

19. Decedent was prescribed the Subject Device while a resident of Horry County, South Carolina, he purchased the Subject Device in Horry County, South Carolina, and the use of the Subject Device occurred in Horry County, South Carolina.

20. Years prior to his death, Decedent used the DreamStation daily, sometimes more than once daily, to treat his obstructive sleep apnea syndrome.

21. At all times Decedent used the DreamStation in accordance with the guidelines, manual and instructions for use set forth by Defendants and as provided to him with the Subject Device.

22. At all times Decedent used the DreamStation for a purpose for which the device was marketed, designed and intended.

23. At all times Decedent used the DreamStation in accordance with the directions and instructions given by his prescribing physician as well as the directions and instructions given by the durable medical equipment provider of the Subject Device.

24. As a result of using the recalled Subject Device, Decedent has suffered personal injuries including harm to his respiratory system, cellular damage, diagnosis of lung cancer, and death. This injury would not have occurred but for the defective nature of the recalled Subject Device and Defendants' wrongful conduct.

25. Decedent's use of the unreasonably dangerous recalled Subject Device was a direct and proximate cause of the development of his lung cancer resulting in invasive treatment and procedures, severe physical pain and suffering, emotional and mental distress, and death.

26. As a result of the aforesaid conduct and recalled Subject Device designed, manufactured, sold, distributed, marketed, advertised and promoted by Defendants, Decedent was injured resulting in invasive procedures and treatment, severe physical pain and suffering, emotional distress and death. As a result of such injuries, Decedent has suffered damages for which compensatory and punitive damages should be awarded.

DEFENDANTS

27. Defendant Royal Philips is a Dutch multinational publicly traded company having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the ultimate parent company of the Philips Group of healthcare technology businesses including Connected Care businesses focusing on Sleep & Respiratory Care. The company, which started as a limited partnership with the name Philips & Co in Eindhoven, the Netherlands, in 1891, was converted into the company with limited liability N.V. Philips' Gloeilampenfabrieken on September 11, 1912. The company's name was changed to Philips Electronics N.V. on May 6, 1994, and then to Koninklijke Philips Electronics N.V. on April 1, 1998, and [finally] to Koninklijke Philips N.V. on May 15, 2013." Royal Philips' shares have been listed on the Amsterdam stock exchange since 1912, have been traded in the United States since 1962, and have been listed on the New York Stock exchange since 1987.23 Royal Philips holds directly or indirectly 100% of its subsidiaries, Philips NA, Philips USA, Philips RS Holding, and Philips RS. As such, Royal Philips controls Philips NA and Philips RS with respect to the manufacturing, selling, distributing, and supplying of the Recalled Devices. Royal Philips

can be served with process via the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters ("Hague Service Convention").

28. Defendant Philips North America LLC ("Philips NA") is a Delaware company with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is a wholly-owned subsidiary of Royal Philips. Upon information and belief, Philips NA manages the operation of Royal Philips's various lines of business, including Philips RS, in North America. The sole member of Philips NA is PHUSA, which is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA has a registered agent in Massachusetts, Corporation Service Company, located at 84 State Street, Boston, Massachusetts 02109. Accordingly, Philips NA is a citizen of Massachusetts and Delaware—the states where its sole member, PHUSA, Inc., is incorporated and has its principal place of business.

29. Defendant Philips Holding USA, Inc. ("PHUSA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. PHUSA is a holding company that is the sole member both of Defendant Philips NA and RS Holding. Accordingly, PHUSA is a citizen of Massachusetts and Delaware.

30. Defendant Philips RS North America LLC f/k/a Respironics, Inc. ("Philips RS") formerly operated under the business name Respironics, Inc. ("Respironics"). Royal Philips acquired Respironics in 2008. Philips RS has a registered agent in Massachusetts, Corporation Service Company, located at 84 State Street, Boston, Massachusetts 02109. Philips RS North America LLC is wholly owned by a single member, Philips RS North America Holding Corporation, which is a Delaware corporation with its principal place of business located at 222 Jacobs Street,

Cambridge, Massachusetts 02141. Philips RS North America is wholly owned by Philips Holding USA Inc. Accordingly, Philips RS is a citizen of Massachusetts and Delaware.

31. Philips RS North America Holding Corporation ("RS Holding") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Cambridge, Massachusetts 02141, and is wholly owned by PHUSA. Accordingly, Philips RS North America Holding Corporation is a citizen of Massachusetts and Delaware.

32. At all relevant times, each Philips Defendant acted in all aspects as the agent and alter ego of one another, and reference to "Philips" refers to each Philips Defendant individually and collectively.

33. Defendant PolyTech is a Delaware corporation with its principal place of business at 420 Corporate Boulevard, Newark, Delaware 19702. PolyTech directly or through another intermediary provided Philips with the PE-PUR foam that was used in the Recalled Devices.

34. Defendant Polymer Molded Products LLC ("PMP") is a Delaware corporation with its principal place of business at 10 Easy Street, Bound Brook, NJ 08805. PMP is a molded polyurethane foam manufacturer. PMP directly or through another intermediary provided Philips with the PE-PUR foam that was used in the Recalled Devices.

35. At all relevant times, Defendants PolyTech and PMP acted in all respects as the agent and alter ego of one another, and reference hereinafter to "PolyTech" or the "PolyTech Defendants" refers to Defendants PolyTech and PMP individually and collectively.

JURISDICTION AND VENUE

36. At all times pertinent to this Complaint, the Philips Defendants were and continue to be in the business of designing, manufacturing, marketing, promoting, advertising and selling devices

for the treatment of obstructive sleep apnea, including the DreamStation prescribed for, purchased and used by the Decedent.

37. At all times pertinent to this Complaint, the Philips Defendants were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to exist.

38. Upon information and belief, Philips Defendants operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and funds, disregarded corporate formalities and used each other as a corporate shield to defeat justice, perpetuate fraud and evade contractual and tort liability.

39. At all times pertinent to this Complaint, the Philips Defendants acted in all respects as agents or apparent agents of one another.

40. At all times pertinent to this Complaint, the Philips Defendants acted in concert in the designing, manufacturing, marketing, promoting, advertising and selling of devices for the treatment of obstructive sleep apnea, including the Subject Device.

41. The Philips Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other, rendering them jointly liable to Decedent.

42. The Philips Defendants regularly transact business in South Carolina that includes marketing and selling devices for the treatment of obstructive sleep apnea, derive substantial revenue from their business transactions in South Carolina, and have purposely availed themselves of the privilege of doing business in South Carolina.

43. The Philips Defendants shipped or participated in shipping the Subject Device and other devices with the reasonable expectation that the devices could or would be purchased and used in the State of South Carolina through the stream of commerce.

44. The PolyTech Defendants manufactured, treated, and processed the PE-PUR foam by, among other things, applying an adhesive backing and an acoustic lining to the foam, which was provided to Philips for integration in the Recalled Devices within the state of South Carolina, and the PolyTech Defendants had a reasonable expectation that its PE-PUR foam could or would be purchased and used in the State of South Carolina through the stream of commerce.

45. Each Defendant has significant contacts in South Carolina and each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them in that they manufactured and supplied materials and Recalled Devices that they knew would be sold to and used by consumers throughout the country.

46. At all times pertinent to the complaint, Decedent was a citizen of the state of South Carolina and suffered injuries in Horry County, South Carolina from the Subject Device.

47. Defendants Philips NA, PHUSA, Philips RS, and RS Holding are each citizens of the states of Massachusetts and Delaware.

48. Defendant Royal Philips is a citizen of The Netherlands and Royal Philips regularly transacts business in South Carolina and therefore receives profits through business transactions in the State of South Carolina.

49. Defendant, Koninklijke Philips N.V. is the parent company of Defendant Philips North America LLC, its largest subsidiary in the United States and it is also the parent company of Defendant, Philips RS North America LLC. Upon information and belief, Defendant, Koninklijke Philips N.V., exercises control over Philips North America LLC with regard to the day-to-day operations of the subsidiary and the conduct underlying this dispute.

50. Upon information and belief, Defendants, Koninklijke Philips N.V. and Philips North America LLC, have overlapping leadership and personnel on the Executive Committee, Board of Management and Supervisory Board.

51. Upon information and belief, the Executive Committee of Defendant, Koninklijke Philips N.V., operates under the chairmanship of the Chief Executive Officer and Supports the Board of Management in the deployment of Philips' strategy and policies, and the achievement of its objectives and results.

52. Upon information and belief, The Supervisory Board of Defendant, Koninklijke Philips N.V., operates as a separate and independent body and supervises the policies of the executive management and the general course of affairs of Philips and advises the executive management.4

53. Plaintiff alleges damages that exceed $75,000, exclusive of interest and costs.

54. Thus, This Court has original jurisdiction in this matter pursuant to 28 U.S.C. § 1332(a)(1)–(2), as there is complete diversity between Plaintiff and Defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

55. Venue is also proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this District as all Defendants, including Royal Philips, designed, manufactured, marketed, promoted, advertised, sold and profited from the Recalled Devices in South Carolina.

56. Further, Defendant Royal Philips is not a resident of the United States, and thus venue is proper in this District under 28 U.S.C. § 1391(b)(3), as it may be sued in any judicial district.

57. This Court's exercise of personal jurisdiction over Defendants comports with due process.

BACKGROUND

58. At all relevant times, Defendants designed, manufactured, marketed, sold, distributed profited from a lineup of CPAP and BiPAP devices as well as mechanical ventilator devices under its "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing and other respiratory conditions, including obstructive sleep apnea syndrome.

59. Instead of adequately testing and assuring the safety of the Recalled Devices, Defendants sought and obtained FDA approval to market the Recalled Devices, including the Subject Device used by Decedent, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of a medical device if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976 and no formal review for safety or efficacy is required.

A. Continuous Positive Airway Pressure Therapy

60. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a nasal or facemask device which helps an individual breathe by increasing the air pressure in an individual's throat.

61. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will

not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance and long-term health.

62. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

B. Bi-Level Positive Airway Pressure Therapy

63. Bi-Level Positive Airway Pressure therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP is distinguishable because BiPAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. BiPAP devices deliver one level of pressurized air (the inspiratory positive level) to assist as a person inhales and another level (the expiratory level) as a person exhales.

C. Philips' Sleep & Respiratory Care Devices Were Endangering its Users

64. The basic technology used in CPAP and BiPAP devices was developed in 1980 by an Australian pulmonologist, Dr. Colin Sullivan, who used it to treat dogs with respiratory problems, before the technology was adapted for humans.

65. Respironics commercialized this technology and sold the first publicly available CPAP device in 1985. ResMed, an industry competitor, followed with the release of its CPAP device in 1989.

66. These first-generation CPAP and BiPAP devices created a new and commercially viable field of respiratory therapy. The devices, however, were large and noisy, resulting in an "arms-race" between manufacturers to develop devices that were smaller, quieter, and more responsive to patient breathing patterns.

67. The noise level of CPAP and BiPAP devices became a driver of adult consumer preference because loud devices interrupted the peaceful sleep of both the patient and their partner.

68. In an attempt to develop quieter devices, some device manufacturers, including Philips, filled the CPAP, BiPAP, and ventilator devices with sound abating foam to reduce the volume of noise emitted from the devices.

69. In fact, the alleged relative quiet nature of the DreamStation products with PE-PUR foam factored prominently into Philips' marketing.100 Philips represents that it extensively studied and measured the amount of sound produced by DreamStation products.

70. Other manufacturers did not utilize foam for sound abatement, instead they utilized silencing technology to abate the sound from the devices.

71. Philips manufactures and sells CPAP and BiPAP machines and ventilators, among other products. According to Royal Philips' 2020 Annual Report,102 Sleep & Respiratory Care ("SRC") constituted 49% of its total sales in its Connected Care line of business,103 which, in turn, accounted for 28% of Royal Philips' overall sales of about €19.5 billion. Philips has sold millions of CPAP, BiPAP, and ventilator devices in the United States and elsewhere throughout the globe. In 2021, there was "a 23% decline in [Royal Philips'] Connected Care businesses. This was largely due to the Respironics recall…"

72. Philips provides a User Manual with its CPAP, BiPAP, and ventilator devices. Royal Philips owns the copyright to all, or most, of those User Manuals.

73. Philips made the decision to use PE-PUR foam for sound abatement purposes in its CPAP, BiPAP, and ventilator devices. That decision was made for products distributed by Philips' entities throughout the globe including, but not limited to the United States, Australia, Canada, Israel, and Chile.

74. Polyurethane is an organic polymer in which urethane groups connect the molecular units.

75. The two main types of polyurethane are polyester and polyether. Polyester polyurethane has better shock absorption and vibration dampening properties and is commonly used for soundproofing or sound dampening.

76. It has been known for decades that polyester polyurethane is susceptible to hydrolysis, the chemical breakdown of a compound due to reaction with water, particularly in medical applications. For example, a chapter of a scientific encyclopedia published in 2013 states: "Poly(ester urethanes) were the first generation of PURs used in medical devices but were found unsuitable for long-term implants because of rapid hydrolysis of the polyester soft segment."

77. Polyether polyurethane, on the other hand, is less prone to hydrolysis. The same scientific encyclopedia chapter notes that polyether polyurethanes "with excellent hydrolytic stability replaced poly(ester urethanes) and have been used in medical devices for the past two decades."

78. There were readily available alternative designs available to Philips, other than to use PE-PUR foam in CPAP, BiPAP, and ventilator devices for sound abatement. These include, for example, other types of sound abating foam and silencing technologies that do not use foam.

79. For example, Philips' principal competitor, ResMed, uses polyether polyurethane foam or silicone-based foam, not PE-PUR foam, for sound dampening.

80. On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time to its shareholders, under a section entitled "Regulatory Update," that device user reports

had led to a discovery that the type of PE-PUR "sound abatement" foam Philips used to minimize noise in several CPAP and BiPAP respirators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."

81. Philips has utilized PE-PUR sound abatement foam to dampen device vibration and sound during routine operation.

82. On June 14, 2021, as a result of ongoing review following the announcement on April 26, 2021, Philips issued a voluntary recall notification for affected devices.

83. In its recall notification, Philips identified examples of potential risks that included exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material.

84. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening, cause permanent impairment or require medical intervention to prevent permanent impairment.

85. According to Philips' recall notice, the PE-PUR foam used in Recalled Devices puts Recalled Device users at risk of suffering from the following health harms: "Particulate exposure can cause headache, irritation [skin, eye, and respiratory tract], inflammation, respiratory issues, and possible toxic and carcinogenic effects[;]" whereas the "potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects."

86. After the devices were sold, Philips had a duty to find, investigate, and report adverse events to the FDA. For example, 21 C.F.R. part 803 requires Philips to conduct a thorough investigation of each event. This duty is triggered when Philips becomes aware of information from any source that reasonably suggests that its device (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned, and, this device or a similar device it markets, is likely to cause or contribute to a death or serious injury, if the malfunction were to recur. 21 C.F.R. § 803.50.

87. Additionally, as a manufacturer, Philips has unique knowledge concerning the frequency, severity and predictability of the complications and risks associated with its devices. Accordingly, Philips has post-market responsibility under the FDA Regulations related to complaint handling, investigation and reporting to the FDA, including but not limited to:

1. 21 C.F.R. § 803.10 (for example, § 803.10(c) requires adverse events to be reported by a manufacturer in set time frames from 5 to 30 days when the event becomes known);
2. 21 C.F.R. § 803.17 ("Medical device manufacturers must develop and implement standardized medical device reporting procedures so that timely evaluation of events and communication of findings can occur.");
3. 21 C.F.R. § 803.18 (§ 803.18(d)(1) requires a device distributor to maintain complaint files and records, including any written, electronic or oral communication, either received or generated by the distributor, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device.);
4. 21 C.F.R. § 803.20 ("Manufacturers must timely communicate a reportable event. Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an

MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.");

5. 21 C.F.R. § 803.3 ("If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.");
6. 21 C.F.R. § 803.50 ((a) "If you are a manufacturer, you must report to the FDA information required by 803.52 in accordance with the requirements of 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." Subsection (b) defines information reasonably known to a manufacturer to include: "[a]ny information that you can obtain by contacting a user facility, importer, or other initial reporter; . . . [a]ny information in your possession; or . . . [a]ny information that you can obtain by analysis, testing, or other

evaluation of the device." Section 803.50 continues: "(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56 in accordance with the requirements of 803.12(a).");

7. 21 C.F.R. § 803.52 (detailed individual and device information must be submitted for each adverse event);
8. 21 C.F.R. § 803.53 (information regarding detailed individual and device information must be submitted in a timely manner when remedial action may be required);
9. 21 C.F.R. § 803.56 (supplemental reporting must be done if additional information is learned that became known after the initial report was submitted); and
10. 21 C.F.R. § 820.198 ("Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event").

88. In addition, there are state law duties to monitor, investigate, evaluate and timely report injuries and other important safety information regarding a medical device, which Philips violated when it failed to: monitor, investigate and report PE-PUR foam degradation risk and incidents; take the necessary steps to continually evaluate the safety, effectiveness and reliability of its Recalled Devices; and take necessary steps to warn, strengthen its warnings, and take other measures to assure compliance with its obligation.

D. Philips Recall and New Product Launch

89. Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall in total.

90. According to FDA Form 483 which was issued to Philips Respironics, Inc. (with dates of inspection of August 26, 2021 through November 9, 2021) the recall targets "…over 15 million Philips Respironics ventilator, CPAP, and BiPAP devices, due to polyester polyurethane foam degradation and volatile organic compound emission, which was publicly announced on 06/14/2021."

91. Philips designs, manufactures and sells CPAP machines, BiPAP machines and mechanical ventilators, among other products. According to Philips's 2020 Annual Report, Sleep & Respiratory Care constituted approximately 49% of Philips's total sales in its Connected Care line of business, which in turn accounted for 28% of Philips's overall sales of about €19.535 billion.

92. Philips's flagship CPAP/BiPAP machine family is known as the "DreamStation" family line, which includes the original DreamStation launched in October 2015, and the DreamStation Go

(a travel version). Philips sells DreamStation products through its subsidiary Respironics that Philips acquired in 2008.

93. Philips' recalled CPAP and BiPAP machines contain PE-PUR foam for sound abatement and air is required to pass through this foam before it is pumped into the patient's airway.

94. On or about April 13, 2021, Philips announced that it was launching the DreamStation 2, the next-generation machine in its DreamStation product family. Interestingly, the DreamStation 2 does not contain the PE-PUR foam for sound abatement.

95. Less than two weeks later, on April 26, 2021, Philips announced in its Q1 2021 Quarterly Report:

> Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone*), and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation
> product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.
> [*)Potential Risks Associated With The Use of Ozone and Ultraviolet (UV) Light Products for Cleaning CPAP Machines and Accessories: FDA Safety Communication.]

96. On June 14, 2021, Philips issued a voluntary recall for many of its CPAP and Bi-Level devices as well as a number of its ventilator devices.

97. Philips issued the following advice to patients using any of the Recalled Devices:

- "For patients using BiLevel PAP and CPAP devices: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."
- "For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps."13

98. Upon information and belief, Philips timed its recall to coincide with the launch of its next generation CPAP platform, DreamStation 2, which purportedly does not suffer from the same PE-PUR foam issues.

99. On the same day, Philips provided additional information in an announcement entitled "Clinical information for physicians," which explained that the foam breakdown "may lead to patient harm and impact clinical care." Philips wrote:

> While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.

100. The announcement by Philips detailed two types of hazards from the PE-PUR foam in the devices: (1) dangers due to foam degradation exposure and (2) possible exposure to chemical emissions from the breaking down of the PE-PUR foam. The first hazard is:

> Potential Hazard: Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.
>
> The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:
>
> a. Toluene Diamine
> b. Toluene Diisocyanate
> c. Diethylene glycol.

101. The European Union considers Toluene Diisocyanate "highly toxic" and has concluded that Toluene Diamine "cannot be considered safe for use" even as a hair dye.

102. Philips disclosed that it "has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."

103. In fact, FDA Form 483 which was issued to Philips Respironics, Inc. (with dates of inspection of August 26, 2021 through November 9, 2021) reflects that "No formal investigation, risk analysis, or CAPA were initiated, performed, or documented, in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017, prior to the initiation of CPAP INV 0988 in 2018."

104. The second hazard is the possibility of VOCs, that is, chemical emissions from the PE-PUR foam. Philips explained:

> Potential Hazard: Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long term adverse health effects.
>
> Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:
>
> a. Dimethyl Diazine
> b. Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)-

105. Philips admitted that the risks of these VOCs include that they "may cause irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve" and may lead to the following symptoms: "headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity,

nausea/vomiting, toxic and carcinogenic effects," as well as "adverse effects to other organs such as kidney and liver."

E. Philips Knew of the Dangers of PE-PUR Foam for Many Years Prior to the Recall

106. At the time it installed PE-PUR foam into the Recalled Devices, Philips was required to test the devices to ensure they were safe for users through the lifecycle of the product, including in accordance with various international standards, for example ISO 18562-2:2017, ISO 18562-3:2017, ISO 10993-13, and ISO 10993-9.

107. At that time, Philips should have known the PE-PUR foam posed a safety risk to users.

108. The FDA concluded after an investigation of Philips' Recalled Devices that beginning in at least 2008, and over time, Philips received hundreds of thousands of customer complaints regarding foam degradation in the Recalled Devices and, years later, received data from a variety of sources confirming foam degradation.

109. The FDA's findings were based, in part, on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021 and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's findings in a 29-page FDA 483 Report issued on November 9, 2021. The FDA delivered the 483 Report to Rodney Mell, Head of Quality at Philips Respironics, on or around November 9, 2021.

110. A 483 Report "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts." These observations are made in a 483 Report "when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been . . . or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health."

111. In connection with the FDA's investigation for its 483 Report, the FDA learned that Philips received hundreds of thousands of complaints from customers about degradation of the foam in its Recalled Devices beginning at least as early as 2008:

> [A] query of your firm's consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices. Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that 30 Trilogy related complaints were received from 2014 to 2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021.

112. Yet, "[n]o formal investigation, risk analysis, or CAPA were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017 . . . ."

113. A Corrective and Preventative Action ("CAPA") refers to procedures that medical device manufactures must follow to identify and attempt to correct a quality problem after one is detected. See 21 C.F.R. § 820.100. A CAPA is designed "to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence."

114. The FDA also found that Philips "was made aware of polyester polyurethane [PEPUR] foam degradation issues in/around October 2015 . . . ." [Indeed, in October 2015, Philips RS Senior Staff Mechanical Engineer Richard Alfieri communicated about the issue with its intermediary Brandon Associates and foam supplier Polymer, saying that "bits of foam have broken away and are pulled into the device."]

115. In fact, an adverse event report from the FDA Manufacturer and User Facility Device Experience ("MAUDE") database shows that, as early as 2011, Philips knew that a patient

discovered "black dust" on her nose when she awoke after using a Philips RemStar CPAP device and subsequently underwent treatment for "intoxication" and "chest tightness."

116. Philips investigated this report and confirmed that the device contained "evidence of an unk[nown] black substance in the air path and on internal components . . . present throughout both the intake and exhaust portions of the air path . . . ."

117. The FDA found that Philips' analysis of consumer complaints was itself defective in that it "was not adequately performed to identify or detect quality problems."The FDA concluded that "potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not likely to occur again, as required by your Health Hazard Evaluation's instructions." In light of this, the FDA concluded that Philips' "risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware" of these issues.

118. Company documents show that Royal Philips authored the Complaint Handling Policy, 8.4-836, utilized by Philips RS in processing complaints related to the Recalled Devices. The Royal Philips Complaint Handling Policy's stated purpose is "to provide a systematic process for the evaluation of customer complaints that have been identified as potentially reportable, and to ensure reporting occurs within statutory and regulatory timeframes to the applicable authorities." As per Royal Philips Complaint Handling Policy, complaints about the Recalled Devices came in globally, were routed to Philips RS for processing, and if a "reportable event" occurred "reports will be filed in other countries in accordance with applicable regulations."

119. Royal Philips Complaint Handling Policy references other Royal Philips policies and documents, including a Royal Philips "Complaint Evaluation, Investigation & Closure" Policy, 8.4-838.227 The stated purpose of this Royal Philips policy is "to control the evaluation of

complaint data (records, service coding, trending, etc.), determine the need for formal investigation, document the results of any executed investigation, and close quality complaints."

120. Indeed, Royal Philips retained ultimate responsibility for the complaint handling process related to the Recalled Devices even after the Recall. When Philips RS undertook a manual review of the complaints identified in response to the FDA's inquiries related to the PE-PUR foam degradation, the review was detailed in a document entitled, "Review of SRC Foam Degradation Complaints," which is on "Respironics" letterhead, but Royal Philips maintains the copyright to that letterhead.

121. The FDA has concluded that:

> Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.

122. The FDA 483 Report notes that "an incorrect and non-specified polyester polyurethane, raw foam product, sourced from your [Philips'] raw foam supplier resulted in [redacted] non-conforming Trilogy Evo ventilatory finished devices being approved, released, and distributed, which further resulted in the ongoing correction and removal." The correction and removal "were established as part of [Philips'] response to failed VOC and ISO 18562 testing of related Trilogy EVO ventilatory medical devices … which resulted from the presence of the nonspecified polyester polyurethane foam component, incorrectly supplied by [Philips'] raw foam supplier."

123. Company documents show that from at least as early as 2016, Royal Philips has demonstrated a systematic level of involvement in and control over testing the PE-PUR foam in the Recalled Devices and investigating the problems with that foam.

124. For example, there is evidence that in December 2014, Royal Philips was aware of complaints of "Black Particles From Airpath Foam" in the Trilogy ventilators originating in Japan, dating back to 2010 device build dates. Similarly, "Foam Separating" complaints in Trilogy ventilators originating in Australia were documented in March 2018, dating back to 2009 build dates.

125. Philips explains that "Innovation & Strategy advances innovation together with Philips' businesses, markets and partners. This entails cooperation between research, design, medical affairs, professional services, marketing, strategy and businesses in a multi-disciplinary fashion, from early exploration to first-of-a-kind offerings." The I&S Hub is also responsible for providing engineering solutions to all of Philips businesses, which is "accountable for bringing engineering capabilities in Philips to world-class level to realize innovations that deliver on our customers' needs. . .Taking a customer-first approach, Engineering Solutions turns ideas into working innovations by providing deep engineering expertise, cross-business product platforms, and innovation processes and tools. Engineering Solutions also works for selected external companies in the healthcare, high-tech and semiconductor industries."

126. Additionally, "The role of Innovation & Strategy is to listen to the voice of the customer and, in collaboration with the operating businesses and the markets, direct the company strategy and innovation roadmap to achieve our growth and profitability ambitions. The various components of Innovation & Strategy include: the Chief Technology Office (CTO), Research, HealthSuite Platform, the Chief Medical Office, Engineering Solutions, Experience

Design, Healthcare Transformation Services, Strategy, and Partnerships. Our four largest Innovation Hubs are in Eindhoven (Netherlands), Cambridge (USA), Bangalore (India) and Shanghai (China)." While the Hub appears to be centered in Eindhoven, Philips also has employees [in the I&S Hub based in Drachten (Netherlands). On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the FDCA, 21 U.S.C. § 360h(b) (the "518(b) Notice"). The 518(b) Notice stated that the FDA's "Center for Devices and Radiological Health (CDRH) is proposing that an order should be issued pursuant to section 518(b)" of the FDCA "to require Philips to submit a plan for the repair, replacement, and/or refund of the purchase price of devices subject to the recall that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial harm to the public health presented by those devices will be eliminated." This notice was directed to Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, for Philips Respironics, Inc.

127. The 518(b) Notice stated that "there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the public health" and "that there are reasonable grounds to believe that the recalled devices that Philips manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices' manufacture."

128. The FDA concluded that "patients and providers cannot readily mitigate the unreasonable risk associated with the recalled devices."

129. The FDA also concluded that "[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR foam."

1. In 2015, Philips Communicated With its Foam Suppliers About The Problem of PE-PUR Foam Degradation

130. The PE-PUR foam that Philips used in its Recalled Devices was manufactured byWilliam T. Burnett & Co. ("Burnett"), a bulk foam manufacturer. Burnett produces foam in sheets that are between approximately four feet to more than six feet wide and may be as long as one hundred or two hundred feet.

131. Burnett sells its bulk foam to intermediaries, including PolyTech and The SoundCoat Company ("SoundCoat"). PolyTech and SoundCoat then sell the foam to Philips, either directly or through another intermediary, such as Paramount Die Corporation, which may modify the foam.

132. According to the FDA, "email correspondence between [Philips] and its raw foam supplier [PolyTech] beginning 10/30/2015 and forward, document that [Philips] was made aware of polyester polyurethane [PE-PUR] foam degradation issues in/around October 2015, which was later confirmed by [Philips'] foam supplier on 08/05/2016, via email."

133. On August 5, 2016, Bob Marsh, a PolyTech employee, wrote to Lee Lawler, an employee of Burnett, referencing a concern expressed by one of its customers, Philips, in the Fall of 2015 regarding foam degradation in its medical devices. Mr. Marsh stated: "They [Philips] are asking again, and wondered if we could give them any estimate on lifespan of the foam when exposed to 40 C and high humidity." Mr. Lawler responded that, under those conditions, he "would not be surprised if ester foam . . . would exhibit signs of hydrolysis in as short a time as a year." He added: "that is not a good environment for polyester foam. Polyether foam could last years in that environment." Presumably referring to Philips, Mr. Marsh responded that he would "let them know they'd be better off with the ether." It was recommended that PMF

(melamine foam) or PAF (polyurethane foam) would be better suited "for high temperature and chemical exposure acoustical absorption."

134. Indeed, Philips RS's Senior Staff Mechanical Engineer Richard Alfieri communicated about this issue with Philips' sales engineer at Brandon Associates and with foam supplier Polytech, saying that "bits of foam have broken away and are pulled into the device."

135. Knowing about these issues with the PE-PUR foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, "this testing spoke only to the limited finding that in the case of the [redacted] foam samples 'returned from service in a Pacific rim location,' spectroscopy results were 'consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material.'" Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.

136. According to the FDA, "no further investigation, health hazard evaluation, risk analysis, or design review was performed or documented by Philips at that time . . . and no preventative maintenance procedures were implemented," other than a limited "preventative maintenance procedure" instituted by a Philips "entity owned by the parent company of Philips Respironics … to replace the air intake assembly of Trilogy ventilator products, due to complaints that had been received regarding degradation of the PE-PUR foam contained in the products." And even then, "Philips did not verify the effectiveness of this measure." As Philips continued to ask its supplier about the properties of the PE-PUR foam and encountered more warning signs, it continued to put that foam in medical devices that millions of its customers were breathing through daily. Testing conducted for Philips in 2016 confirmed that Mr. Lawler from Burnett was correct. According to the FDA, this testing "determined that the PE-PUR foam was susceptible to degradation, resulting in the conclusion at that time that 'polyester urethanes

show bad resistance against high humidity in combination with high temperature.'" Additional testing "determined that, compared to PE-PUR foam, another type of foam, polyether urethane, 'show[s] a far better resistance against high humidity at high temperature.'"

137. The 483 Report identified "at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices." It listed the specific analyses and tests, including one which concluded that "contrary to polyester urethane foams, [redacted] foams shows a far better resistance against high humidity at high temperature."

138. Philips received at least 110 complaints confirmed to be related to foam degradation between 2014 and 2017. Approximately 80 of these complaints concerned CPAP and BiPAP devices.

139. Nonetheless, Philips continued manufacturing and selling the now Recalled Devices containing PE-PUR foam and failed to warn prescribing physicians, durable medical equipment companies ("DMEs") and the patient consumers of this problem.

2. Philips Opened A Formal CAPA in 2019 – But Did Not Initiate A Recall For Two More Years.

140. In April 2019, Philips received two complaints that "sound abatement foam 'is degrading and entering the air path.'"

141. In response, in June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR foam. But as the FDA explains:

> Even then, that CAPA failed to evaluate all relevant data. Philips' search of FDA's Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between

> January 2011 and January 2021. Yet an MDR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips' analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with CAPA INV 0988.

142. Philips continued to test the PE-PUR foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that "the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern…."

143. Another internal "Biological Risk Assessment" dated December 10, 2020 – and "conducted as a result of field reports/complaints regarding degraded sound abatement foam in various CPAP and ventilator products" – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

> The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure. Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.

144. An additional Philips' Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR foam "presents a significant biological risk to patients," and admitted that "[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure."

145. Ultimately, in CAPA 7211, Philips concluded that "the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined

with high humidity" and reiterated that "the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions."

146. Based on its investigation, the FDA concluded that Philips' upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything to rectify or mitigate the hazards:

> [F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021. Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.

F. The Measures Taken by Philips, and by the Royal Philips in Particular, to Recall and Replace the Defective Devices Have Been Inadequate and Ineffective

147. From the outset, Royal Philips has directly overseen and managed the Recall announced on June 14, 2021.

148. Royal Philips tasked a member of its Executive Committee, Roy Jakobs, withleading the company's repair and remediation program. Mr. Jakobs is in charge of Philips'Connected Care businesses that include Philips RS. Royal Philips claims that "[s]ince taking on responsibility for the voluntary recall notification/field safety notice for specific Respironics devices on behalf of Philips, substantial progress has been made under his [Mr. Jakobs'] leadership in the execution of the comprehensive program aimed at delivering a resolution to affected patients as fast as possible in consultation with the relevant competent authorities."

149. In addition to Mr. Jakobs, Royal Philips' Technical Project Manager Jan Bennik "head[s] up the polyester-polyurethane sound abatement foam test and research program." He has spoken publicly on behalf of Philips about the recalled devices.

150. Further, the following additional Royal Philips employees are believed to have knowledge of the Recall of the devices: a) Liz Iversen, Former Chief Quality and Regulatory Officer; b) Jan Kimpen, Chief Medical Officer (Netherlands-based); and c) Carla Kriwet, Former Chief Business Leader Connected Care (Netherlands-based).

151. Upon information and belief, Philips NA has also been involved with the Recalled Devices and the Recall. For example:

- Tom Reimann, Head of Quality of Connected Care, likely "has knowledge regarding the manufacture, regulatory evaluation, and quality assurance review of certain devices and the recall of the devices."
- Thomas Catalano, Director of Product Marketing, is "Lead global product management team in $1 bill sleep business unit." His prior role with Philips was as a Global product Manager, involved with "Development product/service pipeline for next generation of CPAP therapy to treat obstructive apnea."
- Francis Kim, EVP Chief Quality & Regulatory Officer;
- Erin Levering, Medical Safety Manager, was responsible for working "with the Post-Market Surveillance team to assess individual complaints for safety concerns and regulatory reporting requirements.";
- Vitor Rocha, Chief Market Leader – "CEO North America, EVP at Philips…responsible for driving growth, expanding market share and advancing Philips' position…";
- Drilon Saliu, former Connected Care Head of Regulatory Affairs, October 2019 – September 3, 2021368; and
- Jessica Shen, Former Senior Vice President, Global Head of Medical Affairs, Clinical Affairs, HEOR & Regulatory Affairs. April 2015 – August 13, 2021. – "Responsible for pre-market, regulatory approval for commercialization of products and solutions, including the development of key regulatory and clinical strategies to bring new technologies to market with the shortest possible cycle time; and the harmonization of regulatory/clinical processes across all Philips product lines; Work closely with global regulatory officials to further advance Philips' relationship and reputation among these

> important groups; and continue to build out our core internal competencies and strengthen our regulatory, Medical & clinical team."

152. While the Recall began in the United States, it has been expanded worldwide.

153. Since June 2021, Royal Philips has issued numerous press releases specifically providing information about the worldwide recall.

154. Royal Philips also discusses the Recall and the alleged Defect in the products in other communications and press releases such as those about its quarterly results.

155. For example, when the problems with the Recalled Devices were first announced to Philips' shareholders, Royal Philips included in its April 26, 2021 press release regarding First Quarter 2021 results, the following statement from CEO Frans van Houten: "Regretfully, we have identified a quality issue in a component that is used in certain sleep and respiratory care products, and are initiating all precautionary actions to address this issue, for which we have taken a EUR 250 million provision."

156. In the same press release, Royal Philips said: "Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips' sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks."

157. In a June 14, 2021 press release, Royal Philips said: "Philips is initiating a voluntary recall notification to ensure patient safety in consultation with regulatory agencies." Royal Philips CEO van Houten said: "In consultation with the relevant regulatory agencies and in close collaboration with our customers and partners, we are working hard towards a resolution, which includes the deployment of the updated instructions for use and a comprehensive repair and replacement program for the affected devices."

158. This announcement from Royal Philips further stated that "Philips determined based on testing that there are possible risks to users related to this type of foam"; "Philips" decided to issue the recall notification; "Philips has received reports of possible patient impact due to foam degradation"; "Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction"; and "Philips' recently launched next-generation CPAP platform" is not affected by the foam degradation issues.

159. Mr. van Houten also stated in the Recall announcement on June 14, 2021: "We deeply regret any concern and inconvenience that patients using the affected devices will experience because of the proactive measures we are announcing today to ensure patient safety."

160. Later in 2021, Royal Philips emphasized its involvement in the Recall program in various publications. For example, a presentation on Royal Philips' Fourth Quarter 2021 Results noted: "Regular review cadence with Respironics field action Program Management and Executive Committee."The same presentation said: "Philips' experts as well as certified labs and qualified third-party experts are working closely with the Respironics team." The presentation also indicated an effort to "step-up company-wide program."

161. The 2021 Philips Annual Report shows that in addition to Royal Philips' Management, Royal Philips' Supervisory Board and Royal Philips' Quality and Regulatory Committee were also involved in the Recall. For example, the Royal Philips Supervisory Board reported: "In view of the Philips Respironics voluntary recall notification related to the sound abatement foam in certain sleep and respiratory care products (announced on June 14, 2021), the Supervisory Board regularly discussed this issue and the progress made with respect to the repair and replacement program with Management." Further, the Royal Philips Quality and Regulatory Committee reported that, at its meetings, it discussed "matters associated with [the recall], such as interactions with regulatory authorities globally, engagement with patients, physicians, customers and durable medical equipment providers, testing, health hazard evaluations, and the status of the repair and remediation plan."

162. At the May 2022 shareholders meeting for Royal Philips, CEO van Houten said: "Our team is laser-focused on resolving the sleep recall." He added, regarding the recall: "We have established a dedicated team of 1,000 colleagues working under the direct supervision of the Executive Committee." He explained: "I can tell you that the Philips Board of Management became aware of the issue and its potential significance in the first quarter of 2021 and took adequate and immediate action. This resulted in the issuance of the field safety notice and start of the remediation actions in the first half of 2021." Van Houten further stated that [Royal Philips] took a lot of actions. We have, for example, onboarded new top management in the Sleep & Respiratory Care business. We strengthened quality and regulatory affairs leadership for the group for Connected Care, and for the Sleep & Respiratory care business. And we've also added resources to strengthen specific capabilities, all as the consequence of finding out about this issue.

163. Royal Philips' CEO van Houten made frequent statements about the Recall. For example, in the 2021 Royal Philips Annual Report, Mr. van Houten said: "We identified – through our post-market surveillance processes – that the sound abatement foam used since 2008 in certain of our sleep and respiratory care products may degrade under certain circumstances. Subsequently, we issued a voluntary recall notification for affected devices to address potential health risks."In July 2021, he said: "We have mobilized the necessary resources across the company to address the component quality issue in certain of our sleep and respiratory care products."In a January 24, 2022 press release, he said, "we remain extremely focused on repairing and replacing the devices related to the Philips Respironics recall notification." And in April 2022, he said, "[w]e have a strong program management in place overseeing every aspect of the remediation."

164. On the same day that the FDA announced that reports of faulty Philips ventilators and sleep apnea machines had risen, Royal Philips announced that CEO van Houten would be stepping down. CEO van Houten's departure announcement followed a May 2022 Royal Philips shareholders meeting where 80% of shareholders voted against giving Mr. van Houten a bonus. Shareholders were "unhappy about delivery problems and issues with the company's widely used sleep apnea machines."

165. Royal Philips' public statements demonstrate that it has been involved with U.S. regulatory authorities since the announcement of the Recall. In press releases and other statements, Royal Philips has discussed working with the FDA. For example, in a September 1, 2021 press release, Royal Philips said: "Philips received authorization from the US Food and Drug Administration (FDA) for the rework of the affected first-generation DreamStation devices, which consists of replacement of the PE-PUR sound abatement foam with a new material.

Philips anticipates rework to commence in the course of September 2021. In addition to the rework, the company has already started replacing certain affected first-generation DreamStation CPAP devices in the US with DreamStation 2 CPAP devices. Philips remains in dialogue with the FDA with respect to other aspects of the recall notification and mitigation plan in the US."

166. Royal Philips issued the following statement in a November 14, 2021 press release: "'In connection with the voluntary recall notification in June of this year, the FDA has recently conducted an inspection of a Philips Respironics manufacturing facility in the US,' said Frans van Houten, CEO of Royal Philips. 'We will work closely with the FDA to clarify and follow up on the inspectional findings and its recent requests related to comprehensive testing.'"

167. Royal Philips has also stated that it is involved in discussions with the Department of Justice relating to a Proposed Consent Decree. In its press release on Second Quarter 2022 results, Royal Philips said, "the US Department of Justice, acting on behalf of the FDA, recently began discussions with Philips regarding the terms of a proposed consent decree to resolve the identified issues [in inspection of U.S. facilities]."

168. Unfortunately, Philips' "recall" was a recall in name only. It did not effectively provide patients with notice of the risks of the Recalled Devices, nor did it provide them with new Philips CPAP, BiPAP, or ventilator devices.

EQUITABLE TOLLING OF STATUTES OF LIMITATIONS

169. The running of any statute of limitations has been equitably tolled by reason of Defendants' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Decedent, his physicians and durable medical equipment provider the true risks associated with the Recalled Devices.

170. As a result of Defendants' actions, Decedent was unaware and could not have reasonably known or learned through reasonable diligence that he had been exposed to the risks and harms set forth and that those risks and harms were the direct and proximate result of Defendants' acts and omissions.

CAUSES OF ACTION
COUNT I - STRICT PRODUCTS LIABILITY–DESIGN DEFECT

171. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

172. Plaintiff pleads this count under South Carolina's strict liability provision.

173. At all times herein mentioned, Defendants were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the Subject Device, which is defective and unreasonably dangerous.

174. The Subject Device was defective in its design or formulation in that it was not reasonably fit, suitable, or safe for their intended purpose and its foreseeable risks exceeded the benefits associated with its designs. The Subject Device is defective in design because it caused headaches, irritation of the skin, eye and respiratory tract, inflammatory respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting and toxic and carcinogenic effects.

175. The Subject Device is more dangerous than other available devices indicated for similar conditions and uses, and the utility of the device does not outweigh its risks.

176. The defective condition of the Subject Device rendered it unreasonably dangerous and not reasonably safe, and the devices was in this defective condition at the time it left the hands of Defendants. The Subject Device was expected to and did reach Decedent, the supplier of his device and/or his physician without substantial change in the condition in which it was

designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

177. The Subject Device was used for its intended purposes by Decedent and the Subject Device was not materially altered or modified prior to its use.

178. The Subject Device is defective in design because the PE-PUR foam comprising part of the device can degrade into particles that enter the device's air pathway and can off-gas certain toxic and harmful chemicals. These defects caused, among other problems, Decedent's cancer.

179. At or before the time the Subject Device was released into the market and/or sold to Decedent, Defendants could have designed the products to make them less prone to causing health harms, a technically feasible, safer alternative design that would have prevented the harm Decedent suffered without substantially impairing the function of the Subject Device, including not using any PE-PUR foam. In fact, Defendants have purportedly designed such a product with the DreamStation 2.

180. Safer, alternative machines from other manufacturers were available that did not suffer from the defect and did not have an unreasonable risk of harm as with the recalled devices, as well as the Subject Device, and their unsafe PE-PUR foam.

181. The Subject Device did not perform as an ordinary consumer would expect.

182. Decedent was neither able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of the Subject Device. Further, in no way could Decedent have known that Defendants had designed, developed and manufactured the Subject Device in a way as to make the risk of harm or injury outweigh any benefits.

183. The Subject Device was being used in a way in which the Defendants intended at the time it was prescribed and sold to Decedent.

184. Defendants had a duty to create a device that was not unreasonably dangerous for its normal, intended use. Defendants breached this duty.

185. Defendants knew or should have known that the recalled devices, including the Subject Device, would be prescribed to patients and that physicians and patients were relying on them to furnish a safe and suitable device. Further, Defendants knew or should have known that patients for whom the Recalled Devices would be used, such as Decedent, could be and would be affected by the defective design and composition of the devices.

186. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed defective devices which, when used in their intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Decedent, and Defendants are therefore strictly liable for the injuries sustained by Decedent.

187. As a direct and proximate result of Defendants' placement of the Subject Device into the stream of commerce and Decedent's use of the product as designed, manufactured, sold, supplied and introduced into the stream of commerce by Defendants, Decedent suffered damages including but not limited to serious physical, emotional and mental injury, harm, economic loss, wrongful death, survival damages, and other consequential damages.

COUNT II - STRICT PRODUCTS LIABILITY–FAILURE TO WARN

188. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

189. Plaintiff pleads this count under South Carolina's strict liability provision.

190. At all times herein mentioned, Defendants designed, developed, researched, tested and knew or should have known about significant health risks with the Subject Device.

191. At all times herein mentioned, Defendants advertised, promoted, marketed, sold and distributed the Subject Device that was used by Decedent.

192. The Subject Device was expected to and did reach the usual consumers, handlers and persons coming into contact with said devices, without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by the Defendants.

193. Defendants each had an independent duty and continuing duty to warn the medical community, Decedent and Decedent's physicians about the significance health risks and other health harms with the Subject Device.

194. Defendants failed to provide adequate warnings regarding the risks of the PE-PUR foam, and failed to use reasonable care to provide such warnings when Defendants knew of these risks.

195. Defendants had information regarding the true risks but failed to warn the medical community, Decedent and Decedent's physicians. Defendants had such knowledge for years prior to issuing the recall.

196. Despite Defendants' obligation to warn of the significant health risks, Defendants instead chose to actively conceal this knowledge.

197. Decedent would not have purchased, chosen and/or paid for all or part of the Subject Device if he knew of the defects and the health risks of the products.

198. Decedent would not have used the Subject Device if he knew of the defects and the health risks of the products.

199. Decedent used the Subject Device in a manner intended and foreseeable by Defendants.

200. The Subject Device was defective due to inadequate warnings because Defendants knew or should have known that the products created a significantly increased risk of toxic and

carcinogenic effects and more specifically, cancer, among other health impacts and failed to warn the medical community, Decedent and Decedent's physician of the nature of such risks.

201. Defendants omitted and downplayed the significant health risks with the Subject Device that Defendants knew or should have known from previous testing and research even prior to the Subject Device' FDA approval.

202. The Subject Device' labeling and warnings were defective because they omitted and inadequately warned of the devices' health risks.

203. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, Defendants knew that their deliberate omissions would cause physicians, including Decedent's physician, to prescribe the Subject Device without being able to adequately weigh the health risk associated with using the devices.

204. If Defendants would have properly warned about the Subject Device' significant health risk and/or other health harms, no reasonable physician, including Decedent's physician, would have recommended or prescribed the Subject Device because the potential benefits were significantly outweighed by the significant health risk and/or other harms.

205. Had Defendants reasonably provided adequate warnings described herein, such warnings would have been heeded and no healthcare professional, including Decedent's physician, would have prescribed the Subject Device and no consumer, including Decedent, would have purchased and/or used the Subject Device.

206. As a direct and proximate result of Defendants' placement of the Subject Device into the stream of commerce and Decedent's use of the product as designed, manufactured, sold, supplied and introduced into the stream of commerce by Defendants, Decedent suffered

damages including but not limited to serious physical, emotional and mental injury, harm, economic loss, wrongful death, survival damages, and other consequential damages.

COUNT III - STRICT LIABILITY–MANUFACTURING DEFECT

207. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

208. Plaintiff pleads this count under pleads this count under South Carolina's strict liability provision.

209. At all times herein mentioned, Defendants were involved in researching designing, developing, manufacturing, testing, selling and/or distributing the Recalled Devices, including the Subject Device, which is defective and unreasonably dangerous.

210. The Subject Device was expected to and did reach Decedent without a substantial change in its condition.

211. The finished Subject Device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

212. At all relevant times, the Recalled Devices, including the Subject Device, were defectively and improperly manufactured and designed by Defendants in that Defendants continued to supply consumers with the Recalled Devices despite having full knowledge that the devices posed substantial and avoidable bodily injury, including but not limited to toxic and carcinogenic effects and more specifically, cancer.

213. The foreseeable risks of the Subject Device were known and could have been avoided.

214. At all relevant times, the Subject Device were defectively manufactured by Defendants in that its design and formulation is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

215. At all relevant times, Defendants actively deceived users that their use of the Recalled Device posed safety risks that far outweighed any benefits.

216. Furthermore, the Recalled Devices, including the Subject Device, were defectively manufactured in that the PE-PUR foam comprising part of the devices can degrade into particles that enter the devices' air pathway and can off-gas certain toxic and harmful chemicals. These defective Subject Device cause, among other injuries, toxic and carcinogenic effects, and more specifically, cancer.

217. Decedent and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens and other deleterious components and contaminants when using the Recalled Devices including the Subject Device.

As a direct and proximate result of Defendants' placement of the Subject Device into the stream of commerce and Decedent's use of the product as designed, manufactured, sold, supplied and introduced into the stream of commerce by Defendants, Decedent suffered damages including but not limited to serious physical, emotional and mental injury, harm, economic loss, wrongful death, survival damages, and other consequential damages.

COUNT IV – NEGLIGENT DESIGN

218. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

219. At all relevant times, Defendants manufactured, designed, marketed, tested, promoted, supplied, sold and/or distributed the Recalled Devices, including the subject device, in the regular course of business that Decedent consumed.

220. The subject device was designed and intended to be used as for the treatment of sleep apnea and other health issues.

221. Defendants knew or by the exercise of reasonable care, should have known, the use of the subject device was dangerous, harmful and injurious when used by Decedent and consumers in a reasonably foreseeable manner.

222. Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Decedent would not have realized the potential risks and dangers of the subject device.

223. Defendants breached their duty by failing to use reasonable care in the design of the subject device by designing the device such that PE-PUR foam inside the device could produce highly harmful particles and gasses that enter the device's airway leading to the user's respiratory system.

224. The subject device contained and produced chemicals and particles which can lead to headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and cancer, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinary consumers such as Decedent would be victim to.

225. Defendants breached their duty when they failed to use commercially-feasible alternative designs to minimize these harms, including but not limited to designing products that prevented exposure to particles and off-gasses from PE-PUR foam, using a kind of noise and vibration reducing foam that did not possess these harmful qualities, using alternative methods of noise vibration reduction, preventing foam particles and gasses from entering the airway of the product, among many other potential designs.

226. Defendants breached their duty by failing to use reasonable care by declining to include an expiration or best if "used by" date, which left open the potential for the devices' chemical and other properties to change in an even more harmful manner.

227. As a direct and proximate result of Defendants' negligent design, Decedent and/or Plaintiff suffered and will continue to suffer damages for which he is entitled to recover, including but not limited to wrongful death damages, survival damages, compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT V – NEGLIGENT FAILURE TO WARN

228. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

229. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, and/or sold the Recalled Devices, including the subject device that Decedent used.

230. The Defendants knew or, by the exercise of reasonable care, should have known, use of the subject device was dangerous, harmful, and injurious when used by Decedent in a reasonably foreseeable manner.

231. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Decedent would not have realized the potential risks and dangers of the subject device.

232. The Defendants knew or, by the exercise of reasonable care, should have known, that the Recalled Devices posed risks including headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and cancer, among other harmful

effects, as described herein, that were known and knowable in light of scientific and medical knowledge that was generally accepted in the scientific community at the time of design, manufacture, and distribution of the Recalled Devices.

233. The Defendants owed a duty to all reasonably foreseeable users to disclose the risks associated with the use of the Recalled Devices.

234. The Defendants breached their duty of care by failing to use reasonable care in providing adequate warnings to Decedent's physician, in the subject device's labeling and packaging, and through marketing, promoting, and advertising of the subject device.

235. At all relevant times, Defendants could have provided adequate warnings and instructions to prevent the harms and injuries set forth herein, such as providing full and accurate information about the Recalled Devices to physicians, to patients, in advertising, at point of sale, on the devices' instructions and inserts, and on the devices' labels.

236. A reasonable company under the same or similar circumstances would have warned and instructed of the dangers.

237. Decedent was injured as a direct and proximate result of Defendants' failure to warn and instruct because he would not have used or purchased the subject device had he received adequate warnings and instructions that he could be exposed to toxic and carcinogenic particles and gasses that cause headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, toxic chemicals, and cancer.

238. Defendants' lack of adequate and sufficient warnings and instructions and its inadequate and misleading advertising, labeling, and instructions to physicians was a substantial contributing factor in causing the harm to Decedent.

239. Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI – NEGLIGENT MANUFACTURING

240. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

241. At all relevant times, the Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, and/or sold the Recalled Devices, including the subject device that Decedent used.

242. The Defendants had a duty to use exercise reasonable care in the manufacturing, assembling, inspecting and packaging of the subject device.

243. The Defendants knew or, by the exercise of reasonable care, should have known, use of the subject device carelessly manufactured, assembled, inspected, and packaged was dangerous, harmful and injurious when used by Decedent in a reasonably foreseeable manner.

244. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Decedent would not have realized the potential risks and dangers of the subject device improperly manufactured assembled, inspected, and packaged.

245. Without limitation, the Defendants breached their duty to exercise reasonable care in manufacturing, assembling, inspecting, and packaging the Recalled Devices by their:

a. Failure to follow Good Manufacturing Practices (“GMPs”);

b. Failure to adequately inspect/test the Recalled Devices during the manufacturing process;

c. Failure to adequately determine/test the integrity of PE-PUR foam and its qualities, especially after the devices have aged.

d. Failure to adequately determine/test the purity of airflow through the Recalled Devices' airway, especially after the devices have aged.

246. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality of their devices.

247. Decedent and/or Plaintiff was/were injured as a direct and proximate result of Defendants' failure to use reasonable care in the manufacturing, assembling, inspecting, and packaging of the subject device as described herein.

248. The Defendants' negligent manufacturing, assembling, inspecting, and packaging of the subject device was a substantial factor in causing Decedent's and Plaintiff's harms.

249. Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII – NEGLIGENCE / GROSS NEGLIGENCE

250. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

251. Defendants had a duty to exercise reasonable care in designing, developing, researching, testing, manufacturing, marketing, supplying, promoting, selling, and distribution of the Recalled Devices, including the subject device.

252. Defendants knew or should have known that using the subject device created a significantly increased risk of cancer, among other health harms.

253. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Defendants designed and developed the Recalled Devices without thoroughly or adequately testing the devices;
b. Defendants sold the Recalled Devices without making proper and sufficient tests to determine the dangers to the users;
c. Defendants failed to adequately and correctly warn the Decedent, the public, and the medical community, of the cancer risks associated with the Recalled Devices;
d. Defendants advertised and recommended the use of the Recalled Devices for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of cancer risks;
e. Defendants failed to exercise reasonable care in designing the Recalled Devices in a manner which was dangerous to the users;
f. Defendants negligently manufactured the Recalled Devices in a manner which was dangerous to the users;
g. Defendants failed to exercise reasonable care when they collectively decided to conceal information concerning cancer risks;
h. Additionally, Defendants under-reported, underestimated, and downplayed the serious dangers of the Recalled Devices' association with cancer and other health harms.
i. Defendants negligently compared the safety risk and/or dangers of the subject device with other forms of treatment for sleep apnea and similar conditions.
j. Defendants also failed to warn Decedent, prior to actively encouraging the sale of the subject device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early detection of cancer.
k. Defendants specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate warnings regarding all adverse side effects—namely cancer—associated with the use of the subject device.
l. Once Defendants gained additional information about the Recalled Devices' association with cancer, it failed to update its warnings and thereafter accompany the Recalled Devices with adequate warnings regarding cancer.
m. Despite the fact that Defendants knew or should have known that the Recalled Devices caused unreasonably dangerous side effects, like cancer, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute, and/or sell the devices to physicians and patients, including the Decedent.
n. Defendants knew or should have known that consumers, such as Decedent, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

254. Defendants' negligence was the proximate cause of Decedent's cancer-related injuries, among many other health harms, which Decedent and/or Plaintiff suffered and/or will continue to suffer.

255. As a result of the foregoing acts and omissions, the Decedent was caused to suffer serious and dangerous side effects that led to his lung cancer, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment, monitoring and/or medications, fear associated with developing cancer and death.

256. As a result of the foregoing acts and omissions the Decedent required health care and services and did incur medical, health, incidental, and related expenses.

COUNT VIII – NEGLIGENT MISREPRESENTATION

257. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

258. Defendants had a duty to exercise reasonable care to those whom they provided device information about the Recalled Devices and to all those relying on the information provided, including Decedent, his healthcare providers, and the public in general that the devices had been tested and found to be safe and effective for treating sleep apnea.

259. Defendants, in the course of selling the Recalled Devices, supplied information about the devices through television commercials, advertisements, marketing campaigns, sales representatives, labeling, and warnings.

260. Defendants breached their duty by misrepresenting the Recalled Devices' safety to the medical and healthcare community, to the Decedent, and the public in general.

261. However, Defendants failed to exercise reasonable care because their goal should have been to put safety before their profits by providing individuals with the realistic risks and expectations that the Recalled Devices could cause cancer and other serious injuries.

262. Defendants' representations were made without properly conducting sufficient testing and by providing insufficient warnings about the Recalled Devices' potential risks.

263. Defendants' false representations that the Recalled Devices were safe for consumers and their failure to disclose material past and existing facts of the Recalled Devices' risk of cancer were made or omitted with the intent to induce Decedent to rely upon those facts or omissions.

264. Decedent was unaware and did not know that the subject device was unsafe for the purpose of treating sleep apnea because it caused a significant increased risk of cancer until after he had been exposed to carcinogenic particles and gasses.

265. Decedent justifiably relied upon the false representations of Defendants.

266. Had Defendants reasonably and proposed provided adequate warnings of cancer and other serious injuries, such warnings would have been heeded and no healthcare professional, including Decedent's physician, would have prescribed the Recalled Devices and no consumer, including Decedent, would have purchased and/or used the Recalled Devices.

267. As a direct and proximate result of the foregoing acts and omissions, Decedent was caused to suffer serious, dangerous and fatal side effects, including lung cancer, as well as other severe and personal injuries which were permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for medical treatment before his death.

268. As a result of the foregoing acts and omissions, Decedent required more health care and services and did incur medical, health, incidental, and related expenses.

COUNT IX – FRAUD

269. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

270. At all relevant times, Defendants designed manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers, such as Decedent.

271. Defendants knowingly made fraudulent statements regarding the safety of the Recalled Devices and the substantial health risks associated with using the devices, all the while intending to deceive Decedent and the general public.

272. At all reasonable times, Defendants fraudulently misrepresented the Recalled Devices as safe, when in fact the devices posed unreasonable risks of substantial bodily injury.

273. Due to these and other features, the Recalled Devices are not fit for their ordinary, intended use as treatment devices for sleep apnea and similar respiratory conditions.

274. Defendants touted the Recalled Devices as safe, despite a failure to adequately research or test the devices to assess their safety prior to marketing and promoting their use.

275. Defendants further falsely represented the nature and risks associated with the Recalled Devices, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

276. Defendants' fraudulent misrepresentations and omissions were material facts that were essential to Decedent's decision to purchase the subject device.

277. Decedent was unaware that Defendants were knowingly concealing these material facts, which Decedent relied on to his detriment.

278. By knowingly misrepresenting this material information, Defendants breached their duty to protect Decedent and consumers.

279. Decedent justifiably relied to his detriment on Defendants' fraudulent statements. Had Decedent been adequately informed of the material facts concealed from him regarding the safety of the subject device, and not intentionally deceived by Defendants, he would not have acquired/purchased or used the subject device.

280. As a direct and proximate result of Defendants' fraudulent misrepresentations, Decedent suffered and continues to suffer from the injuries and damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorney fees.

COUNT X – FRAUDULENT CONCEALMENT

281. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

282. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that used the devices, such as Decedent.

283. Defendants had a duty to disclose material facts about the Recalled Devices that would substantially affect Decedent's and the general public's use when purchasing the devices.

284. At all reasonable times, Defendants fraudulently misrepresented the Recalled Devices as safe, when in fact the devices posed unreasonable risks of substantial bodily injury. Therefore, the devices are not fit for their ordinary and intended uses.

285. Defendants actually knew about all of the above facts.

286. At all relevant times, Defendants fraudulently and deceptively concealed their failure to adequately research or test the Recalled Devices to assess their safety before marketing to susceptible users.

287. Defendants further falsely represented the nature and risks associated with the Recalled Devices, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

288. Defendants' misrepresentations and omissions were material facts that were essential to Decedent's decision making when purchasing and using the subject device.

289. Decedent was completely unaware that Defendants were concealing these material facts.

290. Defendants intentionally deceived and concealed material information concerning the safety of the Recalled Devices from Decedent and the general public, which had a direct impact on Decedent's and consumers' health and wellbeing.

291. Decedent relied to his detriment on Defendants' fraudulent concealment and omissions. Had Decedent been adequately informed of the material facts regarding the safety of the Recalled Devices, and not intentionally deceived by Defendants, he would not have acquired/purchased, used, or been injured by the subject device.

292. As a direct and proximate result of Defendants' fraudulent concealment, Decedent suffered and continues to suffer from the injuries and damages for which he is entitled to recovery, including but not limited to wrongful death damages, survival damages, compensatory damages, consequential damages, interest, costs, and attorney fees.

COUNT XI – CIVIL CONSPIRACY

293. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

294. Defendants knowingly agreed, contrived, confederated, and/or conspired to defraud Decedent and consumers of the Recalled Devices regarding the true nature of the devices and their potential to cause cancer and other serious injuries associated with the PE-PUR foam's particles and chemicals when the devices were used in a reasonably foreseeable manner.

295. Defendants knowingly agreed, contrived, confederated, and/or conspired to defraud Decedent and consumers of the Recalled Devices with the purpose of maintaining the popularity and reputation of the devices and therefore maintaining high sales, at the expense of consumer safety.

296. At all relevant times, pursuant to and in furtherance of said conspiracies, the Defendants performed the following overt and unlawful acts:

a. Defendants designed and sold the Recalled Devices with full knowledge that the devices were not a safe way to treat sleep apnea.
b. Upon information and belief, despite available medical and scientific data, literature, and test reports possessed by and available to Defendants, Defendants individually, jointly, and in conspiracy with each other, fraudulently, willfully, and maliciously, to delay reporting to the public the issues and delay the product recall. In the meantime, Defendants continued to represent the Recalled Devices as safe and omitted warnings about serious side effects.

297. Decedent and the general public reasonably relied upon the aforementioned fraudulent representations, omissions, and concealments made by the Defendants regarding the nature of the Recalled Devices.

298. Were it not for Defendants' unlawful actions to mislead the public and limit the natural dissemination of scientific research and knowledge on the dangers and harms associated with the Recalled Devices, Decedent and the general public could have learned of the dangers at an earlier date and potentially prevented their introduction to and use of the devices.

299. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of the Recalled Devices which were made pursuant to and in furtherance of a common scheme,

and Decedent's reliance thereon, Decedent and Plaintiff suffered and/or continues to suffer from the injuries and damages for which Plaintiff is entitled to recovery, including but not limited to wrongful death damages, survival damages, compensatory damages, consequential damages, interest, costs, and attorney fees.

COUNT XII – UNJUST ENRICHMENT

300. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

301. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Devices into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that used the devices, such as Decedent.

302. Defendants were unjustly enriched as a result of their wrongful conduct, including through the false and misleading marketing, promotions, and advertisements that failed to discuss the unreasonable risks of substantial bodily injury resulting from the use of the Recalled Devices. Defendants were also unjustly enriched through their developing, manufacturing, promoting, and selling the Recalled Devices without adequately testing and investigating their potential side effects and health impacts.

303. Defendants requested and received a measurable benefit at the expense of Decedent in the form of payment for the subject device.

304. Defendants appreciated, recognized, and chose to accept the monetary benefits Decedent conferred onto Defendants at the Decedent's detriment. These benefits were the expected result of Defendants acting in their pecuniary interests at the expense of its customers.

305. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain these benefits because the benefits were procured as a result of their wrongful conduct.

306. Defendants wrongfully obfuscated the harm caused be their conduct. Thus, Decedent, who mistakenly enriched Defendants by relying on Defendants' fraudulent representations, could not and did not know the effect that using the subject device would have on Decedent's health.

307. Acceptance of the benefit by Defendants under these circumstances would be inequitable.

308. Decedent and Plaintiff are entitled to restitution of the benefits Defendants unjustly retained and/or any amounts necessary to return Decedent and Plaintiff to the position Decedent occupied prior to dealing with Defendants. Given the importance of respiratory health and severity of injuries the subject device can cause, Defendants were reasonably notified that Decedent would expect compensation from Defendants' unjust enrichment stemming from their wrongful actions.

309. Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, medical monitoring to diagnose injuries from the subject device at an earlier date to allow for timely treatment and prevention of exacerbation of injuries, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XIII - BREACH OF EXPRESS WARRANTIES

310. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

311. Defendants, through their advertising, promotional materials and labeling, expressly warranted and affirmed that the Subject Device was safe for their intended uses and for uses which were reasonably foreseeable.

312. Defendants' representations became a basis of the bargain.

313. Defendants made express warranties which extended beyond delivery of the Recalled Devices, including the Subject Device, and expressly warranted for future performance of the devices. Defendants advertised, promoted and labeled the Subject Device as being safe and effective for the treatment of sleep apnea.

314. At all relevant times, Defendants breached said express warranties in that the Recalled Devices, including the Subject Device, was unsafe and caused severe injury. Decedent foreseeably used the Subject Device without knowing of the harmful and substantial consequences to his health.

315. At all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices, including the Subject Device, when used.

316. At all relevant times, Defendants willfully failed to disclose the defects and health risks of the Subject Device to Decedent, his healthcare providers and the rest of the public that used the Recalled Devices.

317. In reliance upon the express warranties made by Defendants, Decedent acquired/purchased and used the Subject Device, believing the Subject Device was inherently safe and/or a safe treatment for sleep apnea.

318. As a direct and proximate result of Defendants' breach of their express warranties concerning the Subject Device, Decedent suffered damages including but not limited to serious physical, emotional and mental injury, harm, economic loss, wrongful death, survival damages, and other consequential damages.

COUNT XIV - BREACH OF THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

319. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

320. At all relevant times, Defendants, through their advertising and promotional materials, expressly and impliedly warranted and affirmed that the Recalled Devices' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

321. Defendants touted the Recalled Devices as safe, despite knowingly having never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

322. Defendants intended to make Decedent and the general public believe the Recalled Devices were safe.

323. Defendants knowingly mislead Decedent and the general public to believe the Recalled Devices were safe for use, despite knowing that the devices could lead to serious injuries, all of which Defendants knew, or by the exercise of reasonable care, should have known, ordinary consumers such as Decedent would be victim to.

324. At all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Devices when used.

325. At all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Devices to Decedent and the consuming public.

326. Decedent relied to his detriment on the information publicized by Defendants.

327. In reliance upon these implied warranties as to the safety of the subject device by Defendants, Decedent acquired/purchased and used the subject device, believing that the subject device was inherently safe.

328. Decedent notified Defendants of the breach.

329. As a direct and proximate Defendants' warranties concerning the subject device, as described herein, Decedent and Plaintiff suffered and/or continues to suffer from the injuries and damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XV - BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

330. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

331. At all relevant times Defendants have been a merchant in regard to the Recalled Devices they created and sold to consumers.

332. Defendants breached their implied warranty of merchantability since the Recalled Devices were defective when created and designed, and do not conform with the promises represented on their labels.

333. Defendants failed to comply with merchantability requirements, as the Recalled Devices do not achieve the ordinary purposes they advertise: a healthy treatment for respiratory conditions such as sleep apnea.

334. Beyond Defendants' own direct sales of the Recalled Devices, Decedent and other consumers are third-party beneficiaries of Defendants' agreements with its distributors, dealers, and sellers for the distribution, dealing, and sale of the Recalled Devices to consumers. Decedent and consumers are the intended beneficiaries of Defendants' implied warranties since the Recalled Devices are manufactured with the express and intended purpose of selling the devices to consumers.

335. As a direct and proximate result of Defendants' breach of their implied warranties of merchantability regarding the subject device, Decedent was damaged because, had he been aware of the unmerchantable condition of the subject device, he would may have not acquired/purchased the subject device and not suffered injuries and damages from their use, for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorneys' fees.

COUNT XVI – VIOLATION OF THE SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT

336. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

337. Decedent was a "consumer" as defined in the South Carolina Unfair Trade Practices Act in that Decedent acquired/purchased, other than for purposes of resale, goods from the Defendants.

338. Defendants' actions in marketing, advertising, and otherwise making public representations about the subject device constitute "trade" as defined by the South Carolina Unfair Trade Practices Act as they were actions that created, altered, repaired, furnished, made available, provided information about, or, directly or indirectly, solicited or offered for or effectuated a sale, lease, or transfer of consumer goods.

339. At all relevant times, Philips knew that the Recalled Devices posed serious health risks to users—the FDA itself concluded that Philips was aware of foam degradation issues and yet delayed doing anything to rectify or mitigate the hazards. Indeed, beginning in at least 2008, and over time, Philips received hundreds of thousands of customer complaints regarding foam degradation in the Recalled Devices and, years later, received data from a variety of sources

confirming foam degradation. In light of these customer complaints, Philips contacted its foam supplier in 2015 about the potential for degradation of PE-PUR foam and in 2016 the supplier confirmed such risks. Philips itself conducted testing in 2016, which determined that the PE PUR foam was susceptible to degradation and off-gassing. Despite its knowledge that the Recalled Devices posed serious health risks to users, Philips continued manufacturing the Recalled Devices with PE-PUR foam, and at no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in its Recalled Devices that could result in serious bodily injury.

340. At all relevant times, Defendants, through their labeling, promotion, and marketing of the Recalled Devices, intentionally misrepresented material facts in order to mislead consumers that the devices were safe and effective for the treatment of sleep apnea.

341. Defendants mislead consumers regarding the substantial health risks associated with using the Recalled Devices constituting a misrepresentation of unlawful trade practices under the South Carolina Unfair Trade Practices Act.

342. Defendants falsely represented themselves when claiming that the Recalled Devices did not pose unreasonable and substantial risks to their health, and thus violated the South Carolina Unfair Trade Practices Act by marketing their goods or services to be of a particular standard, quality, grade, style, when they are/were in fact another.

343. Decedent acted in reasonable reliance upon Defendants' unlawful trade practices through Defendants' misrepresentations and omissions. Had Defendants not engaged in the deceptive conduct described herein, reasonable consumers and Decedent would not have acquired/purchased the Recalled Devices if they had known the devices posed unreasonable and substantial risks to their health. Knowledge of these material factors would have highly

impacted the Decedent's decision when first acquiring/purchasing and using the subject device.

344. Defendants omitted material facts misleading consumers about the safety and efficacy of the Recalled Devices, thus violating the South Carolina Unfair Trade Practices Act.

345. Philips owed Plaintiffs a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other parties who are not Plaintiffs) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

346. As a direct and proximate result of the unlawful trade practices of Defendants, in violation of the South Carolina Unfair Trade Practices Act, Decedent and/or Plaintiff suffered and/or will continue to suffer damages for which they are entitled to recovery, including but not limited to compensatory damages, consequential damages, treble or per-violation damages, interest, costs, attorneys' fees, and all other damages cognizable under the South Carolina Unfair Trade Practices Act.

COUNT XVII – SURVIVORSHIP AND WRONGFUL DEATH

347. Plaintiff re-alleges and incorporates by reference the allegations set forth throughout the Complaint as if set forth herein and further alleges as follows:

348. This claim is brought against the Philips Defendants and the PolyTech Defendants.

349. Plaintiff's Decedent suffered and incurred a premature and untimely death as a result of the Recalled Device.

350. Decedent would not have used the Recalled Device but for the wrongful conduct of Philips and PolyTech. Similarly, as alleged throughout this Complaint and as incorporated herein, Philips and PolyTech are liable for the Decedent's suffering and death, for the survivors' damages, for damages sustained by the Decedent's estate, and all other injuries and damages flowing from the Decedent's death.

351. Plaintiff demands judgment against Philips and PolyTech and requests compensatory damages, punitive damages, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just.

PUNITIVE DAMAGES

352. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

353. Defendants' conduct described herein consisted of oppression, fraud and/or malice, and was done with advance knowledge, conscious disregard of the safety of others and/or ratification by Defendants' officers, directors, and/or managing agents.

354. Despite their knowledge of the propensity of the Recalled Devices to cause serious injuries, Defendants chose profits over the safety of its consumers and American citizens suffering with sleep apnea when they sought to create and market devices posing significant health risks.

355. Despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants intentionally and recklessly failed to adequately warn the public, physicians and the medical community.

356. Further, despite having substantial information about the Recalled Devices' serious and unreasonable side effects, Defendants failed to make the decision to pull the devices from the

market after receiving indications and after receiving reports from consumers who were experiencing serious injuries associated with the use of the devices.

357. Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Devices' potential for causing serious injuries.

358. Defendants chose to do nothing to warn the public or medical community when they knew about serious and undisclosed side effects associated with the Recalled Devices.

359. Defendants recklessly failed to warn and adequately instruct physicians, including Decedent's physician, regarding the increase in reports from consumers who were experiencing serious injuries associated with the use of the Recalled Devices.

360. Defendants' acts were willful, wanton and malicious and showed a total disregard for human life and human suffering.

361. Such conduct justifies and aware for punitive damages in an amount sufficient to punish Defendants' conduct and deter like conduct by Defendants and other similarly situated entities in the future.

362. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, as personal representative of the Estate demands judgment against the Defendants jointly and severally for damages, including punitive damages if applicable, to which he is entitled by law, as well as all costs of this action, interest and attorneys' fees, to the full extent of the law, whether arising under the common law and/or statutory law, including:

a. Judgment for Plaintiff and against Defendants;

b. Damages for the benefit of the surviving statutory beneficiaries in such amount as shall fairly, justly and adequately compensate for their losses occasioned by the aforesaid acts of the Defendants;

c. Damages for the benefit of the Estate of the deceased on account of the pain, suffering, economic loss, and other damages occasioned by the aforesaid acts of the Defendants in such amount as may and shall fairly, justly and adequately compensate for the loss;

d. Pre and post judgment interest at the lawful rate;

e. Punitive damages, if applicable, on all applicable Counts as permitted by the law;

f. A trial by jury on all issues of the case;

g. An award of attorneys' fees and costs; and

h. For any other relief as this Court may deem equitable and just, or that may be available under the law of another forum to the extent the law of another forum is applied, including but not limited to all reliefs prayed for in this Complaint and in the foregoing Prayer for Relief.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

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